



DEPARTMENT OF COMMERCE

Patent and Trademark Office

[Docket No. PTO-P-2023-0014]

Grant of Interim Extension of the Term of U.S. Patent No. 9,314,630; Symplicity Spyral® system, Symplicity Spyral® catheter, and Symplicity G3 generator

AGENCY: United States Patent and Trademark Office, Department of Commerce.

ACTION: Notice of interim patent term extension.

SUMMARY: The United States Patent and Trademark Office has issued an order granting a one-year interim extension of the term of U.S. Patent No. 9,314,630 ('630 patent).

FOR FURTHER INFORMATION CONTACT: Ali Salimi, Senior Legal Advisor, Office of Patent Legal Administration, by telephone at 571-272-0909 or by email to ali.salimi@uspto.gov.

SUPPLEMENTARY INFORMATION: 35 U.S.C. 156 generally provides that the term of a patent may be extended for a period of up to five years, if the patent claims a product, or a method of making or using a product, that has been subject to certain defined regulatory review. 35 U.S.C. 156(d)(5) generally provides that the term of such a patent may be extended for no more than five interim periods of up to one year each, if the approval phase of the regulatory review period is reasonably expected to extend beyond the expiration date of the patent.

On March 23, 2023, Medtronic Ireland Manufacturing Unlimited Company, the owner of record of the '630 patent, timely filed an application under 35 U.S.C. 156(d)(5) for an interim extension of the term of the '630 patent. The '630 patent claims a method of using the product Symplicity Spyral® system, which includes the Symplicity Spyral catheter and the Symplicity G3 generator. The application for interim patent term extension indicates that a Premarket Approval Application (PMA) PMA-220026 was submitted to the Food and Drug Administration (FDA) on March 15, 2015, and that the FDA's review thereof is ongoing.

Review of the interim patent term extension application indicates that, except for permission to market or use the product commercially, the '630 patent would be eligible for an extension of the patent term under 35 U.S.C. 156. Because it appears the approval phase of the regulatory review period will continue beyond the expiration date of the patent, i.e., April 8, 2023, interim extension of the '630 patent's term under 35 U.S.C. 156(d)(5) is appropriate.

An interim extension under 35 U.S.C. 156(d)(5) of the term of U.S. Patent No. 9,314,630 is granted for a period of one year from the expiration date of the '630 patent.

Robert Bahr,

Deputy Commissioner for Patents,

United States Patent and Trademark Office.

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